

DPP® Micro Reader

Read this User Guide completely before using the product.

Storage conditions: Store between -30 to 80°C (-22 to 176°F)

NAME AND INTENDED USE

The DPP® Micro Reader is for use with DPP® Test Kit Devices.

SUMMARY AND EXPLANATION

The DPP® Micro Reader is a reflectance reader for use with DPP® Assay System Devices. The Micro Reader includes a Radio-Frequency Identification (RFID) Card which uses wireless technology to load configuration specific to the test being conducted onto the reader. Once configured, the reader measures the intensity of the control and analyte lines on the test device, and shows the test results on the LCD display. The DPP Micro Reader minimizes human errors due to subjective visual interpretation; therefore, the results of DPP Assay System Devices made to be read with a DPP Micro Reader cannot be visually interpreted by the operator; they have to be read exclusively with the DPP Micro Reader.

PRINCIPLES OF THE PROCEDURE

The DPP Micro Reader is a portable, battery-powered instrument that records the reflectance of the test strip surface and uses assay-specific algorithms to interpret the test and control line reflectance intensities, and establishes the presence or absence of the test analyte(s) in the sample. The reader verifies the presence and intensity of the control line and measures the line intensity at each of the test line positions; it interprets the results using a scoring algorithm, and reports a reactive, non-reactive, or invalid result after approximately 3 seconds.

A 14-segment liquid crystal display (LCD) on the top of the instrument shows the status and results to the operator. The reader supports different assays through assay-specific Radio-Frequency Identification (RFID) Cards which upload wirelessly the software required to correctly analyze and interpret the results of the test being conducted.

The instrument is maintenance-free, not configurable by the user and is designed with a single, multi-function button.

MATERIALS PROVIDED

Each kit contains:

- 1 DPP Micro Reader
 - Dimensions: 41 L x 41 W x 40 H mm (1.6 x 1.6 x 1.6 in.)
 - Weight: 40 g (1.4 oz)
- 3 Lithium-ion Coin Cell batteries
 - CR2032 (3 V/230 mAh)
- 1 DPP RFID Card, test specific
- 1 Micro Reader-specific USB power cord
- 1 US AC 110-240 V to DC 5 V Power Supply
- 1 DPP Cartridge Holder
- 1 Certificate of Analysis

ACCESSORIES REQUIRED BUT NOT PROVIDED

Country-specific AC 110-240 V to DC 5 V Power Supply adapter.

WARNINGS AND PRECAUTIONS

For In Vitro Diagnostic Use.

- Where indicated, DPP Assay test results **must be read using the DPP Micro Reader** and may not be visually interpreted.
- The DPP Micro Readers are produced, calibrated and checked before shipping under strict quality control measures in order to guarantee a high degree of quality. **Do not attempt** to open, re-configure or re-calibrate the Micro Reader.
- RFID cards are provided for running the assay tests. Each RFID card is specific to the assay type being conducted and the RFID card transfers test specific information to the reader before each measurement. Using a wrong RFID card can affect the test results.
- Metal surfaces can influence the RFID card. When configuring the reader, always place the RFID card on top of the reader display to ensure best readability of the configuration information.
- Protection provided by this equipment may be impaired if the equipment is used in a manner not consistent with the instructions in this manual.
- The DPP Micro Reader requires three (3) CR2032 (3 V/230 mAh) batteries to operate or must be powered through the USB cable connected to an external power source.
- Do not use the DPP Micro Reader in direct sunlight or exposed to bright light while reading results.
- The DPP Micro Reader is designed for use on a flat, horizontal surface area.
- Always ensure that the DPP Micro Reader is positioned correctly on the DPP Cartridge Holder. An incorrect positioning may lead to faulty results.
- The DPP Micro Reader can be operated at temperatures between 10 and 35°C (50 to 95°F) and between 20% and 85% humidity. Ensure that the Micro Reader is brought to operating temperature before performing testing.
- Protect the DPP Micro Reader from any liquids. Any liquid entering the Micro Reader can damage it permanently.
- The DPP Micro Reader is designed for use only with DPP test kit devices.
- Please follow the instructions in the product insert provided with the test kit regarding the disposal of DPP test kit devices containing hazardous or infectious material.
- The DPP Micro Reader itself contains no biological hazards. However, contamination due to biological hazards is possible. For cleaning and maintenance, refer to section on **CLEANING AND MAINTENANCE**.

STORAGE AND STABILITY

The DPP Micro Reader should be stored at temperatures between -30 to 80°C (-22 to 176°F) and between 20% and 85% humidity. It should be operated at temperatures between 10 to 35°C (50 to 95°F) and between 20 % and 85 % humidity.

READER MEMORY AND BATTERY LIFE

The reader is not configurable by the user and does not store any data in its memory. If the DPP Micro Reader is being stored in its "off" mode, the batteries will last for about 4 months. If the DPP Micro Reader is being used continuously, the battery will last for approximately 4 to 5 hours, or 200 to 300 tests. The batteries are replaceable. Always have a spare set of three batteries available for replacement. Please see section on **BATTERY INSTALLATION** below. Alternatively, the DPP Micro Reader can be powered using the USB cable and AC 110-240 V to DC 5 V Power Supply, battery pack, or computer USB outlet.

The Radio-Frequency Identification (RFID) Card is not configurable by the user and is DPP assay-specific. Each card comes with the name of the product it is to be used with, and a LOT number for identification purposes.

UNPACKING AND SET-UP

1. Before using the DPP Micro Reader, visually inspect the contents for damage. If damage is apparent, contact Chembio Diagnostic Systems, Inc. at +001 631 924 1135.
2. Remove the reader from its protective wrapping. It is recommended that the packaging materials are retained in a safe location.
3. Ensure that the reader and components are clean. Remove any dust or debris with a smooth, dry cloth.

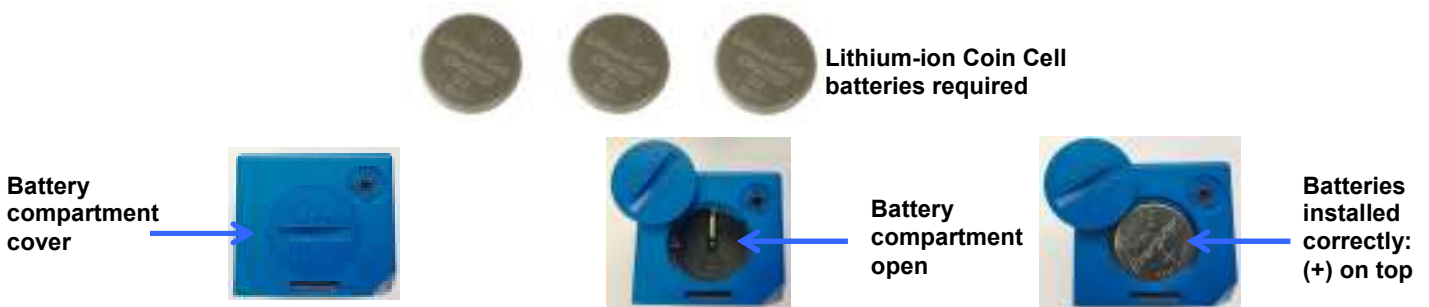


BATTERY INSTALLATION

The reader requires three (3) CR2032 (3 V/230 mAh) batteries, Lithium-ion Coin Cell batteries such as Energizer™ ECR2032 3V LITHIUM; DURACELL DL2032B4 Battery, 2032, Lithium, 3V or equivalent. Replace the batteries when the battery symbol starts to blink. To replace the batteries, turn the battery cover with a smooth-edged coin counterclockwise until it stops. Tilt the device down, and collect the battery cover and the batteries. Place three new Lithium-ion Coin Cell batteries one by one into the battery compartment, with correct polarity orientation ('+' sign up, see Fig. 1). Replace the battery cover by pressing slightly with a coin and turning clockwise until it stops.

NOTE: In case the device does not start after putting in new batteries please check the polarity and clean the batteries by using a dry cloth.

Figure 1: Battery Installation / Replacement



After turning on the device for the first time or after changing the batteries, the date and time need to be set. Please refer to the next section, **SETTING DATE AND TIME**.

SETTING DATE AND TIME

When the DPP Micro Reader is off, the display is blank.



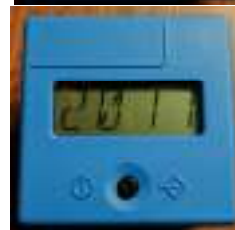
To turn on the device, press the Operating button briefly (i.e. less than 1 second).



After activation, an alarm can be heard, and the display shows 'ON'.



Press the Operating button shortly twice (<1 second). Year, date and time will appear on the display.



Press the Operating button for approximately 1 second, a flashing display appears with the first time specification: year. By repeated short (<1 second) pressing of the button, the displayed value can be changed. When the wanted value is reached (i.e. year 2016) press the button longer (>1 second); the appointed value will be stored and the next time information will be presented. Repeat these steps to successively set the year, month, day, hour and minute. After setting the date and time information, the device will display 'OK'.



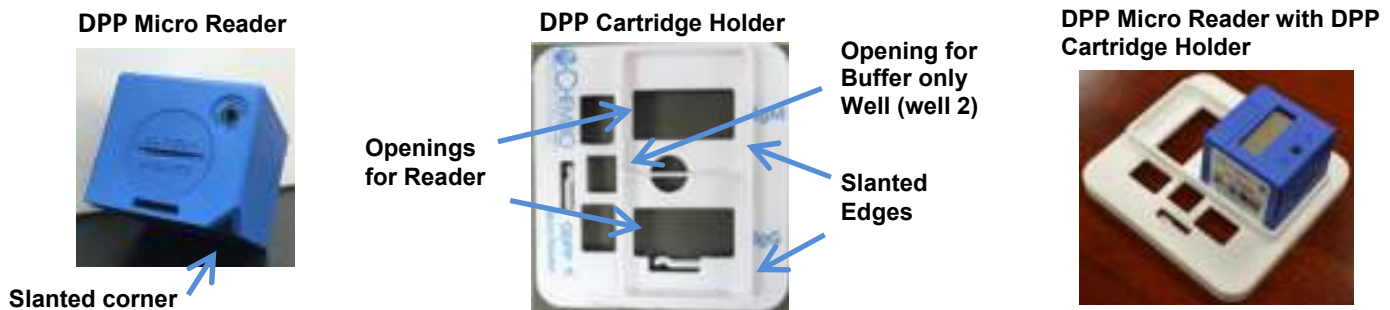
Press the button one more time (< 1 second), the reader will show 'ON' and is now ready for use. Repeat this process after every battery change.



PROCEDURES FOR USE

The DPP Micro Reader is intended for use with DPP test kit devices. Specific instructions and expiration dating (format: YYYY-MM-DD) for the DPP test kit devices can be found in the labeling included with each device test kit.

Connect the DPP Micro Reader to the supplied holder as shown below. There is only one correct way to match the reader with the holder. Insert the base of the reader so that the “slanted” corner meets the corresponding “slanted edge” in the holder cavity. The reader should lay flat in the holder and the button and battery compartment should face the sample well and the user.



Reading DPP Test Result

At the time indicated for reading the test results,

1. Place the cartridge holder on top of the DPP test cassette. Make sure it clicks into place.
2. Place the reader in the opening of the cartridge holder that corresponds to the window that the DPP test kit product insert indicates should be read first.
3. Press the button briefly (less than 1 second): “ON” should appear in the display window.
4. Press the button again (< 1 second) and the display will then call for the RFID card.
5. Place the RFID card on top of the reader to allow the reader to obtain assay information and then remove it after the alarm indicates that the card was read.
6. Press the button one more time (<1 second) and reader will show “RUN”. After a few seconds, an audible alarm occurs and the results of the DPP test will scroll across the display. Write down the results.
7. Move the reader to the second opening in the cartridge holder.
8. Follow the test specific instructions in the Product Insert.



Turning Off the reader

When a measurement is completed, the reader will turn off automatically after approximately 50 seconds of inactivity. There is no active function to shut off the Micro Reader.

CLEANING AND MAINTENANCE

The outer case and display may be cleaned with a towel lightly moistened with 70% isopropyl alcohol (IPA), 10% bleach solution, or mild soap solution. Do not introduce cleaning solution or any liquid into the unit. Do not use a saturated towel, which may leak liquid into the case or display seams. Ensure that the DPP Micro Reader is dry and the surface is free of fluid prior to returning to use.

Make sure that the window under the reader is clean of finger marks, dust and lint, which may interfere with the results. It can be wiped with a dry cloth, or with 70% isopropyl alcohol (IPA) to remove greasy or finger marks.

SERVICING

There are no user serviceable components in the unit with the exception of the replaceable batteries. For technical issues or questions, please contact Chembio Diagnostic Systems, Inc. at +001 631 924 1135.

DISPOSAL OF THE READER

As the DPP Micro Reader may be contaminated by infectious material, it should be disinfected according to the **CLEANING AND MAINTENANCE** section above before disposal. Remove the batteries before disposing of the expired device and dispose of the batteries in accordance with local regulations.

MESSAGES

Messages displayed by the DPP Micro Reader are described in the table below. For assay-specific messages, see the appropriate package insert.

Message	Type	Meaning	Action Recommended
ON	Status	Reader is ready for use.	None
RFID	Status	Reader is ready for RFID card.	Place the RFID card on top of the reader to allow the reader to obtain assay information. Remove it after the alarm sounds.
TEST	Status	Reader is ready to run a DPP test device.	Press the button and the reader will show RUN.
RUN	Status	Reader is reading test results.	None.
OK	Status	Reader has recorded date and time information.	Press the button one more time, the reader will show 'ON' and is now ready for use.
ERR	Error	The device could not read the information from the RFID card.	(1) Press the button briefly (<1 second), the display will show 'ON'. (2) Verify that correct RFID card is being used. (3) Make sure the RFID card is on top of the reader after you press the button when the RFID word is in the display. If the error occurs again, please contact Chembio Diagnostic Systems, Inc.
DATE	Error	An expiry date appears to be exceeded.	Check the expiration date of the reader, RFID card and the test device in use.

SPECIFICATIONS

Dimensions:	L x W x H: Approx. 1.6 x 1.6 x 1.6 in. (41 x 41 x 40 mm)
Weight:	Approx. 1.4 oz (40 g)
Operation:	One button operation
Display:	14-segment LCD
Storage capacity:	None
Device measurement period:	Approx. 3 seconds
Power supply:	3 batteries CR2032 (3 V/230 mAh) Or Micro-Reader power cord/USB cable
Interface:	4 pole – 0.1 in. (2.5 mm) jack plug for power supply (instead of battery)
Configuration:	Specific configuration program; RFID technology
Measuring field:	Min. 0.2 in. (4 mm) width; Max. 0.7 in. (18 mm) length
Lighting:	Wavelength 525 nm
Signaling device:	Buzzer
Operating conditions:	Between 50°F (+10°C) and 95°F (+35°C); between +20 % and +85 % humidity
Storage conditions:	Between -22°F (-30°C) and 176°F (+80°C); between +20 % and 85 % humidity
Degree of protection:	IP 20
Lifetime:	3,000 reads

ORDERING INFORMATION

REF 65-9553-0 Chembio DPP Zika IgM/IgG System

REF 70-1049-0 Chembio DPP Zika IgM/IgG Micro Reader

For Product Information please email info@chembio.com
















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SYMBOL LEGEND	
	CONSULT THE MANUAL BEFORE USE
	CAUTION, CONSULT THE ACCOMPANYING DOCUMENTS
	FOR USE WITHIN TEMPERATURE LIMITS
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	BATCH CODE
	PRODUCT CATALOG NUMBER
	MANUFACTURERS IDENTIFICATION
	DATE OF MANUFACTURE
	USE BY DATE
	THIS DEVICE SHOULD BE TREATED AS WASTE EQUIPMENT AND DISPOSED OF AT DESIGNATED COLLECTION POINT
	READER POWER ACTUATION (ON/OFF)
	READER SERIAL NUMBER (13 DIGITS)
	PROTECTION CLASS OF ELECTRONIC EQUIPMENT